

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	David H. Coar	Sitting Judge If Other than Assigned Judge	
CASE NUMBER	01 C 7631	DATE	5/2/2003
CASE TITLE	Oakwood Laboratories, et. al. v. TAP Pharmaceutical Products, Inc., et. al.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

Claim Construction

DOCKET ENTRY:

- (1) ☐ Filed motion of [use listing in "Motion" box above.]
- (2) ☐ Brief in support of motion due _____.
- (3) ☐ Answer brief to motion due _____. Reply to answer brief due _____.
- (4) ☐ Ruling/Hearing on _____ set for _____ at _____.
- (5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (7) ☐ Trial[set for/re-set for] on _____ at _____.
- (8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.
- (9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
- (10) ☒ [Other docket entry] Claims 15, 16, and 17 of the '542 patent are construed as set forth in the attached Memorandum Opinion and order.

David H. Coar

- (11) ☒ [For further detail see order attached to the original minute order.]

<input type="checkbox"/> No notices required, advised in open court. <input type="checkbox"/> No notices required. <input type="checkbox"/> Notices mailed by judge's staff. <input type="checkbox"/> Notified counsel by telephone. <input checked="" type="checkbox"/> Docketing to mail notices. <input type="checkbox"/> Mail AO 450 form. <input type="checkbox"/> Copy to judge/magistrate judge.	courtroom deputy's initials klb (lc)	MAY 5 2003 date docketed <i>UP</i> docketing deputy initials date mailed notice mailing deputy initials	Document Number	
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DOCKETED

MAY 15 2003

OAKWOOD LABORATORIES, L.L.C., and)
UNIVERSITY OF KENTUCKY)
RESEARCH FOUNDATION,)

Plaintiffs,)

v.)

TAP PHARMACEUTICAL PRODUCTS,)
INC., TAP HOLDINGS, INC., TAKEDA)
CHEMICAL INDUSTRIES, LTD., and)
ABBOT LABORATORIES,)

Defendants.)

No. 01 C 7631

HONORABLE DAVID H. COAR

MEMORANDUM OPINION AND ORDER

Oakwood Laboratories, LLC filed suit against TAP Pharmaceutical Products alleging that it infringed U.S. Patent No. 4,818,542 (the "542 patent") by manufacturing and selling sustained release leuprolide acetate products. On April 4, 2003, this Court held a hearing in accordance with Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed.Cir.1995). This Court's construction of the claims at issue in this case is set forth below.

I. Legal Standard

In Markman, the Federal Circuit held, and the Supreme Court affirmed, that it is the courts' responsibility as a matter of law to construe the claims of patents for the jury. 52 F.3d at 979. Claim construction is "the process of giving proper meaning to the claim language," the fundamental process that "defines the scope of the protected invention." Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed.Cir.1997). Claim construction analysis must begin with the

words of the claim, which define its scope. Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002). "[T]he language of the claim frames and ultimately resolves all issues of claim interpretation." Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed.Cir.1997).

The words used in the claims are interpreted in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history, if in evidence. Teleflex, 299 F.3d at 1324. The intrinsic evidence may provide context and clarification about the meaning of claim terms. Id. In the absence of an express intent to impart a novel meaning to claim terms, there is a "heavy presumption" that a claim term carries its ordinary and customary meaning. Teleflex, 299 F.3d at 1325. The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including the claims themselves, other intrinsic evidence including the written description and the prosecution history, and dictionaries and treatises. Id. (citations omitted). In all cases, however, the ordinary meaning must be determined from the standpoint of a person of ordinary skill in the relevant art. Id.

Of all the intrinsic evidence, courts have indicated that the specification is the "single best guide to the meaning of a disputed term." Vitronics, Corp. v. Conceptiontronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "Usually, it is dispositive." Id. In Teleflex, the court indicated that "[o]ne purpose for examining the specification is to determine if the patentee has limited the scope of the claims." 299 F.3d at 1325. As an example of such an instance, the court said "an inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention with reasonable clarity, deliberateness, and precision." Teleflex, 299 F.3d at 1325. In addition, the specification may be consulted to resolve ambiguity if the ordinary and customary meanings of the words used in the claims are not sufficiently clear to allow the scope of the claim

to be determined from the words alone. Id. "The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Id.

On the other hand, while the claims must be read in view of the specification, limitations from the specification are not to be read into the claims. Id. at 1326. "That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." Raytheon Co. v. Roper Corp., 724 F.2d 951, 957 (Fed.Cir.1983). The Teleflex court sought to explain this seeming contradiction:

If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with "claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. It is the claims that measure the invention.

299 F.3d at 1326. The Teleflex court distilled these concerns to hold that "claims take on their ordinary meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of the claim scope." 299 F.3d at 1327.

More recently, the Federal Circuit addressed this seemingly ambiguous area of law in Texas Digital Systems, Inc., 308 F.3d 1193 (Fed.Cir.2002), where it held that:

the intrinsic record also must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted. Indeed, the intrinsic

record may show that the specification uses the words in a manner clearly inconsistent with the ordinary meaning reflected, for example, in a dictionary definition. In such a case, the inconsistent dictionary definition must be rejected. In short, the presumption in favor of a dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.

308 F.3d at 1204 (citations omitted). It would appear, then, that the intrinsic record, including the specification, would generally "trump" the claim language in construing the claim. The court, however, went on to caution:

Consulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims. For example, if an invention is disclosed in the written description in only one exemplary form or in only one embodiment, the risk of starting with the intrinsic record is that the single form or embodiment so disclosed will be read to require that the claim terms be limited to that single form or embodiment. Indeed, one can easily be misled to believe that this is precisely what our precedent requires when it informs that disputed claim terms should be construed in light of the intrinsic record. But if the meaning of the words themselves would not have been understood to persons of skill in the art to be limited only to the examples or embodiments described in the specification, reading the words in such a confined way would mandate the wrong result and would violate our proscription of not reading limitations from the specification into the claims.

308 F.3d at 1204-05 (citations omitted).

If the meaning of the disputed terms are still ambiguous after consideration of intrinsic evidence, courts will consider extrinsic evidence. Kopyake Enters., Inc. v. Lucks Co., 264 F.3d 1377, 1381 (Fed Cir. 2001). Although a dictionary is considered extrinsic evidence, "[j]udges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the

dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n. 6 (Fed.Cir.1996).

Once the court has ascertained the meaning to one of ordinary skill in the art of the disputed term, the court will examine the written description and drawings to be certain that the patentee's use of the term is consistent with the meaning determined by the court. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Rexnord, 274 F.3d at 1342 (quoting Vitronics, 90 F.3d at 1583). The drawings and written description are examined "to determine whether the patentee has disclaimed subject matter or has otherwise limited the scope of the claims." Rexnord, 274 F.3d at 1343. The court should also examine the prosecution history to determine whether the patentee has ascribed a special meaning to the term that is inconsistent with the term's ordinary meaning. Vitronics, 90 F.3d at 1582. Furthermore, any meaning that was disclaimed during the prosecution of the patent as revealed by the prosecution history is excluded. Vitronics, 90 F.3d at 1583.

II. Discussion

The parties dispute the construction of Claims 15, 16, and 17. Each of the claims will be considered in turn.

A. Claim 15

Claim 15 of the patent reads "A drug delivery system comprising a spherical microporous polymeric network of interconnecting channels containing a drug wherein said drug is distributed essentially within the channels of said microporous polymeric network."

The parties first argue over whether “a drug delivery system” is a preamble that has no legal effect. “[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.” Bell Communications Research, Inc. v. Vitalink, 55 F.3d 615, 620 (Fed. Cir. 1995) (citations omitted). “In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” Cataline Mktg. Int’l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002). Conversely, “where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.” Rowe v. Dror, 112 F.3d 473, 478 (Fed.Cir.1997). Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed.Cir.2001). In this case, the preamble states the intended use for the invention, i.e. a drug delivery system. The preamble was not relied upon to distinguish the claimed invention from the prior art. Thus, it does not impose a claim limitation. Nonetheless, the Court construes the phrase “drug delivery system” to mean “a system for administration of drugs.”

The parties agree that the term “spherical” in Claim 15 means “globe-like”. The parties next dispute the meaning of “microporous.” Plaintiffs argue that “microporous” means having extremely small pores. Defendants, on the other hand, equate the term “microporous” with

“microporosity,” and construe the claim to mean having extremely fine porosity and a specific surface area greater than 12 m²/g. The term “microporosity,” however, does not appear in Claim 15 of the ‘542 patent. Porosity is specifically mentioned in Claim 23 of the patent. Thus, the inventor drew a distinction between porosity and porous. If the applicant intended to use porosity, he would have done so. The Court will construe the claim term that is in the Claim, “microporous,” not the claim term that the defendants believe is equivalent to the term used. See U.S. v. Teletronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988) (“There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims.”) (citations omitted).

The defendants next argue that plaintiff disclaimed any specific surface area less than 12 m²/g in the prosecution history. Specific surface area is one way to measure porosity. Defendants argue that the inventor used specific surface area measurements to distinguish the invention in the ‘542 patent from the Fong prior art microspheres. The ‘542 applicants told the examiner that the invention “always had a surface area greater than 12 m²/g,” whereas Fong’s specific surface area was less than or equal to 12 m²/g. Thus, defendants argue that the applicants disclaimed claim coverage for specific surface areas 12 and under. See Spring Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 994 (Fed. Cir. 2003) (“It is well established that the ‘prosecution history limits the interpretations of claim terms so as to exclude any interpretation that was disclaimed during prosecution.”). Plaintiffs argue that nothing in the prosecution history justifies reading any porosity limitations into Claim 15. Although declarations filed in the ‘542 prosecution history report microsphere porosity data for prior art microspheres of Fong and those of the ‘542 invention, plaintiffs maintain that those declarations

were not relied upon to differentiate the '542 claims from the microspheres of the Fong prior art on the basis of porosity. In fact, the '542 prosecution history shows that the declarants said the porosity of Fong microspheres was "irrelevant in terms of drug release because the [Fong] drug does not appear to reside in the pores." '542 PH, Declaration dated March 31, 1986, at p. 4. As further stated in the prosecution history, "Declarants further determined that any porosity attributable to the Fong microspheres was misleading since the drug did not reside in the pores," and that "*the drug in the Fong microspheres is not located in the inside lining of the pores.* Thus the instantly claimed method and drug delivery system are distinct from those of Fong." (Emphasis in original). '542 PH, Reply and Amendments dated March 31, 1986, at p. 9. The plaintiffs assert that it is clear from the prosecution history statements that novelty over Fong leading to patentability did not at all rely upon any measurement of porosity, but rather upon the location of the '542 drug compared to the location of the drug disclosed in Fong. Thus, according to plaintiff, there was no self-imposed porosity limitation which can be read into the '542 claims as a disclaimer. Defendants, relying upon Spring Windows Fashions, argue that the applicants statements distinguishing prior effect a disclaimer even if not accepted by the examiner, and even if not necessary for patentability. 323 F.3d 989, 994.

The defendant's argument fails because it relies heavily on its claim that "microporous" is equivalent to "microporosity." It appears that the defendants' argument that "microporous" and "microporosity" are the same is based on its desire to bootstrap specific surface area limitations into the claim. The measurements in question are of porosity and this Court rejected the defendants' claim that the term "microporous" is equivalent to the term "microporosity." Thus, it is improper to read specific surface area limitations into the claim when those limitations

are not based upon an interpretation of explicit claim language. See In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1348 (Fed. Cir. 2002) (“limitations appearing in the specification will not be read into the claims, and interpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.”) (quoting Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (emphasis in original)); see also Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed.Cir.1993) (finding that district court erred in interpreting " 'straw-shaped, channel-forming element' limitation to mean 'straw-sized' ... because [the claim] does not impose any requirement as to size.") Accordingly, the cases cited by the defendants to show that remarks made to distinguish the prior art are relevant in claim construction are inapposite because the claim term to be interpreted is “microporous” not “microporosity.”

The parties next dispute the construction of the phrase “polymeric network of interconnecting channels containing a drug.” Plaintiff contends that it means “a polymeric matrix that bounds the walls of an array of passageways within the matrix wherein the drug delivery system contains the drug.” Defendant contends that the claim language means “polymeric object . . . that contains a system of tubular enclosed passages or canals, like a street grid, in which the tubular passages contain a drug, and in which they connect mutually with each other and are open to the surface, wherein the network of interconnecting channels cannot be made by an evaporation technique.” The parties agree that the proper definition of channel is a “tubular enclosed passage.” The parties also seem to agree that network is “a system of channels that cross or interconnect.” In addition, during the Markman hearing, defendants admitted that the reference to “like a street grid” is clearly extrinsic and not critical to the definition of the

claim. Markman Hrg. Tr. at 63, lines 11-22. Thus, for purposes of the claim construction, this Court will disregard the "like a street grid" analogy and it will not become part of the claim.

The parties dispute the construction of "interconnecting" channels. Plaintiffs construe "interconnecting" to mean passageways that communicate with other passageways within the polymer matrix. Defendants would require that *all* passageways "connect mutually" and that the passageways open to the surface. The plaintiffs do not appear to dispute that the passageways must open to the surface. The dictionary definition of interconnect is to connect mutually or with one another. The inventor's illustration in the prosecution history at UKRF 06158, however, schematically illustrates that not *all* channels communicate with other channels. Thus, the intrinsic record trumps the dictionary definition. This Court construes "interconnecting" channels to mean that "most of the passageways connect mutually with each other and are open to the surface."

The parties next dispute "containing a drug." Plaintiff asserts that containing a drug simply means "wherein the drug delivery system contains the drug." Defendant argues, however, that it means "the tubular passages contain a drug." The patent specification states "...the incorporated agents [drug] are matrix confined within the interconnecting channels..." (5:17-22). There is further support in the prosecution history for defendants' construction. The 5-20-85 Reply and Amendment states "[t]he incorporated agent [drug] is confined within the walls and channels of the pores as opposed to random distribution within the more poorly defined interstices of the polymer." Thus, the Court accepts defendants' construction of "containing a drug."

The defendants argue that the claim should be further limited by adding "wherein the network of interconnecting channels cannot be made by an evaporation technique." Claims 13-26 of the '542 patent were initially rejected as anticipated by Fong, a prior-art patent that taught microspheres made by an evaporation technique. The rejection stated that the products of Fong would presumably be microporous. '542 PH, Office Action dated July 29, 1985, at 3 ¶ 3. During the prosecution of the '542 patent, Dr. DeLuca and the applicants made the following statement:

Applicants have determined that it is not possible to obtain a microporous polymeric network of interconnecting channels containing a pore incorporated agent therein by removing the solvent in their process via evaporation. The reason for this inoperability is not understood, however, it is possible that evaporation is just too slow to allow adequate formation of a polymeric network of interconnecting channels.

'542 PH, Preliminary Amendment dated March 31, 1986. Thus, defendants argue that this and other statements act as a disclaimer that should limit Claim 15 of the '542 patent. Unasserted Claims 13 and 14 of the patent, however, are the method claims. That is, they are directed to particular methods of making microspheres, and they specify two alternative processes described and enabled in the '542 specification for removing solvent: "freeze drying" or "dilution - extraction - precipitation." At one time, a third alternative method for removing solvent, using "evaporation," also was recited in the method claims. This alternative step was deleted from the method claims because the inventors believed that a particular type of prior art evaporation process (disclosed by the Fong prior art reference) would not give the desired results. Thus, any disclaimer arising from the deletion of evaporation as an alternative solvent removal step in the unasserted method claims is immaterial to the scope of the asserted product claims. To hold

otherwise would be to read limitations into the claim that are not based upon the claim language.

See Intervet America, Inc., 887 F.2d at 1053.

Finally, the parties dispute the construction of the phrase "wherein said drug is distributed essentially within the channels of said microporous polymeric network." The terms "drug," "channels," and "microporous polymeric network" have already been defined in the claim. Thus, the analysis here need only focus on the meaning of "distributed" and "essentially." Plaintiffs construe the claim language to mean "wherein the drug essentially lines the walls of said passageways." Defendants argue, based on the dictionary definition, that the term "distributed" means "apportioned throughout" the network of channels. The '542 applicants explained that "the agent or drug simply lines the channels or pores." '542 PH, Reply and amendment dated January 29, 1986, at 9-10. They also stated that "the drug is distributed within the interconnecting channels." '542 PH, Amendment after final rejection dated April 18, 1988, at 7. The Court accepts the plaintiffs' definition of "distributed" because it is based upon the intrinsic record. Defendants next argue that "essentially" is a relative term and the Court must determine whether a standard for defining the term is set forth in the patent specification. See Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984) ("When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree.") (construing "substantially"). Defendants argue that the '542 patent specification provides such a standard:

It is evident that the release of the incorporated agent or agents will be essentially complete, i.e. 90%, before any erosion or degradation of the polymer matrix occurs.

'542 Patent, Col. 5, lines 41-44. This standard is further supported by the extrinsic evidence.

Named inventor DeLuca testified:

Q: ... Your understanding of what you meant by almost all [of the drug], how much can be outside of the pores, is there a maximum limit that you would set?

A. The patent states to that "essentially," so 90 percent, ... that was reference to a section essentially all would be incorporated into the channels, ... and I think that's something ... that we kind of stand on.

DeLuca 30(b)(6) Dep. (12/17/2002) at 27. Thus, defendants contend that "essentially" means that at least 90% of the drug is apportioned throughout the network of channels prior to administration. The plaintiffs contend, however, that "distributed essentially" refers to the location of the drug within the channel walls sufficient to accomplish its intended purpose. While the Court agrees that "distributed essentially" refers to the location, the term "essentially" is still a relative term which begs the question "how much is distributed?" The answer is provided in the intrinsic and extrinsic record - 90%. Accordingly, the Court construes the phrase "wherein said drug is distributed essentially within the channels of said microporous polymeric network" as "wherein at least 90% of the drug lines the walls of said passageways."

The defendants seek to add another limitation to Claim 15: "whereby release of essentially all the drug (i.e., 90%) is not dependent upon the physical or chemical erosion or upon hydration (swelling) of the polymer." The prior art depended on the process of hydration for release. Hydration means that when polymeric microspheres are placed in water or administered to the body, the microspheres swell and fill with water. The water also causes the polymer itself to begin to biodegrade, which provides a sustained release of drug from the polymeric matrix. The '542 applicants repeatedly distinguished their method of drug release from these prior-art methods of drug release:

It is relevant to note that the accessibility of the drug or other incorporated agent is not dependent upon the physical or chemical erosion of the polymer for release. The prior art systems generally encapsulate the drug within the polymer thus shielding the drug from the environment around the polymer. Release for these prior art microspheres is, of course, dependent on degradation of the polymer itself or swelling due to hydration and subsequent release by diffusion through the swollen polymer. Applicant's drug lines the walls and channels of the pores in its microsphere. Thus, physical or chemical erosion of the polymer is not necessary for release of the drug.

'542 PH, Amendment after final rejection dated April 18, 1988, at 6 (underlining in original).

There are similar statements in the patent specification. See '542 Patent, column 2, lines 64-68.

Thus, defendants argue that any microsphere that is dependent upon bioerosion or hydration for release of drug was disclaimed. Drug "release," however, is not a limitation of the asserted claim. No release mechanism can be read into the claims because the claim makes no reference to release mechanisms. It is the location and accessibility of the drug within the channel walls that is claimed. Thus, this claim limitation, like the others asserted by defendants, fails because it is not based on the construction of claim language. See Intervet America, Inc., 887 F.2d at 1053.

Thus, the Court construes Claim 15 as follows: "A system for the administration of drugs, wherein said system comprises a globe-like polymeric object having extremely fine pores and containing a system of tubular enclosed passages or canals, in which the tubular passages contain a drug, in which most of the passages connect mutually with each other and are open to the surface, wherein at least 90% of the drug lines the walls of said passageways."

B. Claims 16 and 17

Claim 16 of the '542 patent reads as follows: "The drug delivery system according to Claim 15 wherein said spherical microporous polymeric network is selected from the group consisting of gelatin, agar, starch, arabinogalactan, albumin, collagen, polyglycolic acid,

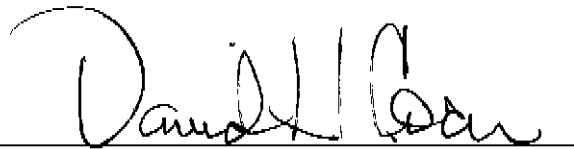
polylactic acid, glycolic-L-(-)lactide copolymer, poly (ε-caprolactone), poly (ε-caprolactone-CO-lactic acid), poly (ε-caprolactone-Coglycolic acid), poly (ε-hydroxy butyric acid), polyethylene oxide, polyethylene, poly (alkyl-2-cyanoacrylate, poly(hydroxyethyl acrylate), polyamides, poly (amino acids), poly(2-hydroxyethyl DL- aspartamide), poly(ester urea), poly(L-phenylalanine/ethylene glycol/1,6- diisocyanatohexane) and poly (methyl methacrylate).” Claim 17 is as follows: “The drug delivery system according to Claim 15 or 16 wherein said polymer comprises a polyester polymer of polyglycolic acid or polylactic acid or a copolymer of glycolide and L(-) lactide.”

Plaintiffs argue that the terms in Claims 16 and 17 should have their ordinary meaning. Defendants contend that Claim 16 refers to “glycolide-L(-)lactide copolymer” and Claim 17 refers to “a copolymer of glycolide and L(-)lactide.” Defendants’ position is that “glycolide-L(-)lactide copolymer” and “L-lactic acid-co-glycolic acid copolymer” are synonymous, and include such copolymers made by any method. The plaintiffs counter that defendants’ construction is based on an erroneous understanding of polymer chemistry. It is not necessary, however, for the Court to determine which understanding of polymer chemistry is correct. See Intervet, 887 F.2d at 1054 (The presumption of validity under 35 U.S.C. ‘ 282 carries with it the presumption that the examiner did his duty and knew what claims he was allowing. In any event, the claims as allowed are what we have to deal with and it is not for the courts to say that they claim limitations which are not in them.) (citations omitted). Accordingly, Claims 16 and 17 shall be given their ordinary meaning. The Court will adopt the plaintiff’s proposed jury instructions for Claims 16 and 17.

Conclusion

For the foregoing reasons, Claims 15, 16, and 17 of the '542 patent are construed as set forth above.

Enter:

A handwritten signature in black ink, appearing to read "David H. Coar", written over a horizontal line.

David H. Coar
United States District Judge

Dated: May 2, 2003